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ABSTRACT

The United States Food and Drug Administration (FDA) collects information in seven areas: foods, cosmetics, human drugs, animal drugs and feeds, medical devices, biologics, and electronic radiological products. By using procedures outlined in the Freedom of Information Act, the public may get specific information from such FDA files as inspection sample results, compliance and regulatory actions, hearing clerk records, FDA administrative files, and reports to the Department of Health, Education, and Welfare. (RL)

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FREEDOM OF INFORMATION CENTER REPORT NO. 407

A GUIDE TO THE FDA

This report was written by Annetta K. Miller, a recent graduate of the University of Missouri School of Journalism.

Tucked away among the Food and Drug Administration's mammoth inventory of forms and files are hundreds of documents known as Establishment Inspection Forms and Analytical Laboratory Worksheets. Contained in these documents is, among other items, an evaluation of the way food-producing industries across the country are complying with the agency's "tolerable filth levels."

The FDA officially set those levels in 1972 to tell food producers exactly how much mold, rot, rodent hair, insect residue, excrement and other unsavory substances it would allow in their products. For example, in peanut butter — staple of the American lunchbox — the FDA will tolerate up to 50 insect fragments or two rodent hairs per 3½ ounces.

Just how much filth actually ends up in the peanut butter Americans spread on their sandwiches? Are certain filth levels unavoidable? By setting such levels, has the FDA, in effect, encouraged adulteration of food rather than assured its purity?

The answers to these questions lie somewhere in that inspection and laboratory information — information that is available to anyone with the time and inclination to pursue it. And yet, it seems, few have done so. Since the initial flurry of news stories and one study by Consumers Union, news coverage of the way FDA filth tolerance levels affect the purity of food has been scarce.

The FDA's inspection and laboratory files represent only a tiny portion of the files the agency is required by law to maintain. There are literally tons of other forms, applications and reports. Why are they overlooked?

Many in the science writing profession believe that the FDA's complex bureaucratic structure and its tendency to be secretive make using FDA records impractical. They prefer to rely solely on human resources. When Washington **Post** science and medical reporter Victor Cohn wants information from the FDA, he says, "I talk to people."[1]

Dan Greenburg, editor of **Science and Government Reports** and author of numerous free-lance articles on health and medicine, understands Cohn's reasoning. Getting information from the FDA, Greenberg says, "is a very, very long and laborious process and most reporters just don't have the time."[2]

Time is not the only factor in reluctance to use the agency. Misconceptions about what the FDA has to offer play a role, too. The agency is often passed over in favor of its regulatory stepsister, the Federal Trade Commission. It is the FTC — involved in food and drug matters because of its role in regulating advertising — that seems to have produced the flashy stories and the banner headlines.

But to overlook the FDA, the original source of information, is to overlook a vast array of potentially useful data. The agency collects information in seven areas: foods, cosmetics, human drugs, animal drugs and feeds, medical devices, biologics and electronic radiological products. This report looks at that information and suggests ways it might be useful.

First, a word of warning: Getting some of the information discussed here will undoubtedly take some digging. A good portion is available only through the Freedom of Information Act. Some — at least officially — is not available at all.

This report is intended to facilitate the digging by providing an overview of information filed with the FDA. (A supplementary section discusses procedures for obtaining that information.)

The FDA Labyrinth

The Food and Drug Administration, with offices in Rockville, Md., and Washington, D.C., functions as the long arm of the consumer — meting out product approvals, setting standards for the public's protection and recalling products when the evidence dictates. The FDA's job is to determine how safe a food, drug, cosmetic or — more recently — medical device is, weighing the risks involved in approving a product for the market.

The main FDA headquarters in Rockville is a labyrinth, employing nearly 5,000 persons in eight different bureaus. The bureaus — foods, drugs, veterinary medicine, radiological health, biologics, medical devices, diagnostic products and toxicological research — contain more than 40 different divisions dealing with matters ranging from medical quackery to mercury vapor lamps.

Just as complex as the FDA's structure is its method of storing information. The White House Office of Management and Budget oversees a total of 67 different forms that various industries must file with the FDA on a regular basis. The OMB also supervises an ever-changing assortment of single-time reports, many of which involve matters of immediate concern to consumers. One recent single-time report, for example, contained results from an FDA survey of persons who

Summary: The Food and Drug Administration collects information in seven areas: foods, cosmetics, human drugs, animal drugs and feeds, medical devices, biologics and electronic radiological products. This report provides an overview of that information and discusses procedures for obtaining it.

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underwent thyroid tests a number of years ago. Another studied the effects of hemodialyzers — artificial kidney machines.

But not all of the information that the FDA collects shows up on forms. Some is located in files of enforcement actions, recall reports, regulatory letters, petitions, and a host of other documents within the national, regional and district FDA offices.

What follows is a description, by program, of some key FDA documents. Also included is information on how to obtain them.

I. Drugs

Almost everyone takes prescription drugs. Almost everyone knows that drugs can save lives and alleviate suffering. But relatively few know of the suffering and waste caused by their misuse. A number of the forms filed with the FDA can provide clues about how safe and effective certain prescription drugs are and how drug companies use and misuse them.

A. Clinical Investigator Files

"It is extremely improbable," Commissioner George P. Larrick assured the Kefauver Subcommittee on Antitrust and Monopoly in 1960, "that falsified or synthetic reports . . . would pass for long the security and review of competent (Food and Drug Administration) scientists without arousing suspicion."[3]

Whatever euphoria that firm assurance by the commissioner was capable of creating was dispelled three years later by a five-count indictment against a suburban Washington doctor. The charges against him were that he had caused pharmaceutical companies to submit erroneous reports on new drugs by supplying them with fraudulent clinical results.[4]

A clinical investigator file, used to evaluate the quality of work performed by doctors testing drugs, was created on him and 19 other doctors accused of fraud in drug testing. Washington **Post** reporter Morton Mintz obtained information contained in the file through a Freedom of Information Act request and used it to help document drug company payoffs to FDA physicians testing their products.

B. New Drug Applications (OMB Form 57-R003)

NDA forms provide an abundance of information about any drug a company is planning to market. Information contained in a new drug application, which usually consists of many volumes of material, includes: chemical makeup, relationship to other chemically or pharmacologically related drugs, dosage forms, purpose of the drug, reference number under which the drug was investigated, findings from the investigation, adverse reactions of patients on whom it was tested, a general evaluation of the safety and efficacy of the drug, and packaging and labeling information.

In the case of the doctor charged with presenting fraudulent research results, medical journal articles in which he praised the products he had "tested" frequently found their way into new drug applications that won FDA clearance.[5]

C. Investigational New Drugs (OMB Form FD-1571)

Before a new drug may be shipped in interstate commerce and tested on human subjects, an application from the drug's producer is required. The IND form is the best source of information about what new drugs are being tested in this country.

D. Community Pharmacists' Drug Defect Report Program (OMB Form 57-R0059)

Interested in what kind of gripes your friendly neighborhood pharmacist hears every day about the medicines he sells? Want to know what products have produced the most complaints? The FDA, in cooperation with the United States Pharmacopoeia, sponsors what is called the Community Pharmacists' Drug Defect Report Program. Under the program, pharmacists are asked to report any problems their customers have mentioned concerning drugs — sickness, rashes, adverse reactions, etc. Reporting materials are mailed to pharmacists three times a year. Completed reports are returned to the U.S. Pharmacopoeia. Upon receipt, that organization immediately forwards copies of the reports to officials in government and industry.

Thus far, more than 20,000 reports have been submitted by both community and hospital pharmacists. Many of the reports have resulted in product recalls by manufacturers. Numerous other reports have brought about improvements.

E. Drug Master File

This file contains confidential information concerning drug producers — their personnel, facilities, drug formulations and production methods.

F. Methadone Hospital Files (Form 57-R0096)

Access to information contained in these files could provide clues to the extent of heroin addiction in a community. The information is kept on any hospital requesting approval to treat heroin addicts with methadone, a legal narcotic used as a heroin substitute. Included in the file are the name and complete address of each physician involved in a hospital's methadone program and a summary of his or her training and experience. The form also includes a statement of the number of addicts to be included in the program. It warns doctors to be on the alert for persons attempting to enroll in more than one methadone treatment program in order to obtain the drug for self-administration or illegal marketing.

G. Drug Experience Reports (Form 57-R0071)

The Health Research Group established by consumer advocate Ralph Nader recently petitioned the FDA to remove clofibrate, a cholesterol-lowering drug, from the market because a new study indicated the drug can cause gallstones.

For those seeking more information about it or any other drug, a good source would be drug experience reports. The reports must be filed by manufacturers any time they receive a complaint about an adverse drug reaction. Physicians and members of the general public also may file the reports, which contain the following information: amount and form of patient dosage, length of time a drug was administered, the reason for use of the drug, a list of the patient's prior disorders and past drug reactions, and reports from laboratory studies and autopsies. The report also lists whether the patient (whose name does not appear on the form) has recovered from his ailments, is still under treatment, is suffering from adverse reactions to the drugs, or is dead.

H. Registration of a Drug Establishment

This form requires the owner of any establishment that sells drugs to list the name of the owner, names and titles of partners, corporate officers and members of the board of directors. Other firm names used by the establishment also must be included.

II. Foods

The largest single part of the FDA's annual budget — 32 percent — is allotted to food safety and regulation. The Bureau of Foods oversees foods produced and stored in 77,000 manufacturing and storage establishments.[6] The following is a guide to the information some of those establishments provide the FDA.

A. Food Additive Petitions (Form 57-R0032)

When producers of saccharin or nitrates seek approval to market their product, a food additive petition is required. The petition includes documentation of the additive's safety. Contained in a related file (the Food Additive Master File) is supporting material from producers such as test results and correspondence between them and the FDA. Still another file (the Food Additive Subject File) contains correspondence with industry, consumers and other agencies concerning the safety and efficacy of an additive. Also included are advisory opinions, data reports and results of evaluations on additives.

B. Color Additive Petitions

The American Dairy Association advertises butter as "One table spread . . . made without chemical preservatives, additives and artificial flavor." The ads do not mention that depending on the time of the year, the butter may be artificially colored. Butter, ice cream and natural cheeses are the only substances exempted from an FDA requirement that a petition be filed whenever a color additive is used in food. The petitions are supplemented by documents relating to manufacturing procedures for additives.

C. Aflatoxin Studies

Aflatoxin, the cancer-causing substance found in moldy nuts, has not aroused as much controversy as its carcinogenic counterparts, nitrates and saccharin. But to those inclined to eat large quantities of peanut butter sandwiches or packages of salted cashews, it is just as important.

Aflatoxin has caused liver cancer in animals and is suspected of causing cancer in humans, although direct proof is lacking. Reports on substances found to contain aflatoxins are filed in the FDA's Bureau of Foods. Also filed are summaries of those reports.

D. Use Data on Red Dye No. 2

The recent furor over Red Dye No. 2 has affected more than maraschino cherries. The dye was used in the production of a vast assortment of drugs, foods and cosmetics. This file contains information from producers and trade associations. It is used to help determine what restrictions should be placed on the additive.

E. "Generally Regarded As Safe" Information

For years, BHT, a substance used to prevent fats and oils from becoming rancid, was an entry on the FDA's "Generally Regarded as Safe" list. But recently, in light of tests on rats which indicated the substance may cause metabolic disturbances, the agency has recommended that BHT be removed from the GRAS list. BHT, still being manufactured, is used in margarine, oils, jams, nut products, cereals, snacks, frozen dairy products, chewing gum, and processed fruits and vegetables.

Information on laboratory tests and scientific evaluation of numerous GRAS substances such as BHT, along with data on their effects on consumers, is contained in the file.

III. Medical Devices

When a Chicago reporter checked his blood pressure at some of the coin-operated screening devices throughout that city, he found alarming discrepancies in their readings. While one machine recorded his blood pressure as normal, another indicated he was suffering from severe hypertension. Other readings fell somewhere in between.

Coin-operated blood pressure machines such as the ones the reporter tested and later wrote about are among the many types of medical devices regulated by the FDA's Bureau of Medical Devices. Under FDA requirements, manufacturers of medical devices file applications with the agency for any new device they plan to market.

The applications contain information on all devices used to diagnose and treat illness — electrocardiograms, pacemakers, blood pressure equipment, etc. They provide clinical data, test results, labeling requirements, promotional material, progress reports, adverse reaction data and related correspondence. Also included are notices of FDA approval and disapproval of such devices.

IV. Radiological Health

Shortly after the recent nuclear accident at Three Mile Island Nuclear Power Plant near Harrisburg, Pa., the FDA was asked to sample foods produced or sold within a 20-mile radius of the plant. Agency employees tested milk, the substance in which radioactivity is most likely to appear first. They also visited a nearby fish hatchery, a drug company and 32 manufacturing firms, where more samples were taken. The sample results are now on file with the FDA Bureau of Radiological Health. The bureau also oversees the 2,800 firms that produce or assemble X-ray equipment or manufacture such products as microwave ovens, television sets, sunlamps and lasers. Among its files is the Standards and Regulations file.

Standards and Regulation Information

The FDA Standards and Regulations file spans a variety of areas. Information contained in it, for example, might provide statistics about residents of Utah believed to have been exposed to radiation. (The FDA recently conducted a survey of those residents asking them to report any adverse reactions that may have resulted from the exposure.)

The file also provides information about another current FDA problem: non-compliance with the federal radiation Safety Performance Standard by members of the medical and dental X-ray industry. For the last three years, the FDA has been inspecting equipment in medical and dental facilities. The results of those inspections have shown a high rate of non-compliance, especially among medical hospitals.

The file also includes information on accidents and radiation exposure, correspondence and drafts of legislation. Names of appointees to the Medical Radiation Advisory Committee, the Technical Electronic Product Radiation Safety Standards Committee and other product safety committees are included.

V. Biologics

The Bureau of Biologics regulates 6,900 blood banks and 1,600 other products such as vaccines and allergy medicines. In 1973, the bureau began a review of all biologic products on the market to assure their safety, efficacy and proper labeling.

A. Source Plasma Manufacturing (Form 57-R0092)

Are the blood donors used by manufacturers of plasma healthy?

To find out, the FDA requires that all manufacturers of plasma complete a license application. The application must include information about donors' physical examinations. It must include the name of the physician and state whether the patient's medical history was reviewed. Evidence must be provided that blood tests for hepatitis and syphilis were taken, that the storage temperature of the blood was correct, and that proper precautions were taken to prevent labeling errors.

B. Efficacy Reviews

The FDA requires efficacy reviews on all products manufactured between 1903 and 1972. Several years ago, for example, the agency did efficacy studies on eight substances used in skin tests for allergies. It also tested 11 bacterial vaccines. The evaluation resulted in the agency's refusal to continue licensing the substances.

Products are evaluated by a panel of experts in such areas as poisons, vaccines, etc. Documents submitted by manufacturers are included in the review.

VI. Veterinary Medicine

A. Investigations

During FDA feed plant inspections, samples of animal feeds are taken and later checked for quantities of heavy metals, pesticides and other harmful residues. Reports on the sample results are filed.

B. Animal Drug Experience Reports

Reports on animals' responses to certain drugs are compiled in the same manner as those on human drug reactions. The animal drug experience reports, as do those for humans, include information on labeling, manufacturing, production and clinical studies. The information is supplied by the producer of the drug, by doctors or by the public.

VII. Cosmetics

Cosmetic Experience Reports (Form 57-R0105)

Hearings by the House Commerce Subcommittee on Oversight and Investigations on cancer-causing substances were held in Washington not long ago. To the surprise of no one, testimony revealed that there were many suspect ingredients in permanent hair dyes, in cosmetics, in some suntan lotions and other products.

The FDA requires cosmetic manufacturing companies, like drug manufacturers, to file experience reports. They provide information about the number of persons using a particular cosmetic who suffered local irritations, allergic reactions, nail damage, infections, etc. They indicate whether those people required medical attention.

The Pink Sheet, a weekly newsletter for executives in drug, cosmetic and related industries, periodically uses information available from cosmetic adverse reaction surveys. The newsletter recently published a report, for example, detailing the kinds of cosmetic adverse reactions that have resulted in serious injuries.

Filings Common to Many Programs:

Inspection Sample Results

FDA's filth tolerances for chocolate products call for no more than 150 insect fragments in one eight-ounce chocolate bar.[7] Although candy bars are usually clean, some manufacturers have taken more care than others.

The FDA enforces its tolerance levels through periodic inspections of candy plants, at which time laboratory specimens are taken. A report on the contents of those specimens is then filed in the FDA district office closest to the plant. (The FDA has district offices in 22 major cities across the country. The district offices are responsible for all local plant inspections.) Similarly, the FDA files sample test results from inspections of all food, drug and cosmetic establishments.

Compliance and Regulatory Actions

A regular feature of the Pink Sheet is a list of the most recent FDA enforcement actions. The FDA initiates corrective action whenever it detects a violation. In some cases, the manufacturer voluntarily corrects the defect. In others, the FDA takes the necessary action, which may include a recall, license suspension, seizure, injunction or prosecution.

The agency classes its recall actions in three categories: Class I — the violative product poses reasonable probability of serious adverse consequences or death; Class II — the violative product may cause temporary or medically reversible adverse health consequences, probability of serious consequences remote; and Class III — the violative product is not likely to cause adverse consequences.

Hearing Clerk Records

When the Health Research Group filed its recent petition calling for the ban of the drug Darvon, that petition was filed in the office of the FDA hearing clerk. It is available to the public. Also available through the clerk are legal briefs, letters from consumers, transcripts of hearings, judges' orders, hearing requests and other legal documents used in proceedings before an FDA administrative law judge.

Administrative Files

Probably the single most important file within the FDA, the administrative file brings together documents from all FDA bureaus and enters them by company.

For example, a file on the Coca-Cola company might in-

clude information on an establishment inspection, violations and corrective enforcement actions. It would include Coca-Cola's applications for marketing new products and correspondence from and about the firm. An index to the administrative file is available in the agency's reading room.

From HEW

Another valuable resource is available from the FDA's parent department — the Department of Health, Education and Welfare. That resource is the Medicare or Medicaid cost report, a report required of any hospital — public or private — seeking Medicare or Medicaid reimbursement. The Medicare/Medicaid cost report is the confessional of the hospital industry: It contains information on cost-charge ratios, mark-up amounts for various services, statistical information on occupancy rates and length of stay, purchasing and billing costs, etc.

The reports are often available, too, on clinics operated by private physicians, providing the clinics perform Medicare or Medicaid services.

Medicare and Medicaid cost reports can be obtained by making a Freedom of Information Act request to the nearest regional office of HEW. The best bet for getting a request into the right hands is to address it to the attention of the Medicare or Medicaid Cost Bureau in any of the 10 offices. Their locations and addresses are listed below.

Atlanta — 101 Marietta St., Atlanta, Ga. 30323
Boston — JFK Federal Building, Boston, Mass. 02203
Chicago — 175 W. Jackson Blvd., Chicago, Ill. 60604
Dallas — 1200 Main Tower Building, Dallas, Texas 75202
Denver — Federal Building, 1961 Stout St., Denver, Colo. 80294
Kansas City — 601 East 12th St., Kansas City, Mo. 64106
New York — 26 Federal Place, New York, N.Y. 10007
Philadelphia — P.O. Box 7760, Philadelphia, Pa. 19101
San Francisco — 100 Van Ness Ave., San Francisco, Calif. 94102
Seattle — Arcade Plaza Building, 1321 Second Ave., Seattle, Wash. 98101

The FDA and the Freedom of Information Act

Few of the hundreds of documents in the FDA are available just for the asking. With the exception of hearing clerk records, most information must be specifically identified and requested through the FOIA (5 USC 552). Information may be obtained by writing: FDA Information Center, Federal Office Building No. 8, 200 St. S.W., Washington, D.C. 20204.

Information may fall within an FOIA exemption and thus not be available. However, information may bypass the FOIA exemptions if the data have been disclosed previously to the public. The FDA makes the determination about whether the information is exempted. A manufacturer may request that the information it submits be kept confidential, but it is up to the agency to make the final decision. Usually, the agency will not disclose information about a product if it is not on the market, or if the producers can prove that there is no intent to market the item.

Alternatives to the Freedom of Information Act

Reporters who cover the FDA frequently say the best way to get information from the agency is to find a reliable source. In lieu of one of those, another source for FDA information not available through the FOIA is the congressional committee report. Since Congress is allowed to poke its nose into any FDA document it wishes, information not generally released by the agency sometimes is made public. The Senate Subcommittee on Monopolies and Anti-Competitive Activities (affiliated with the Small Business Committee), for example, has held a series of hearings on problems within the drug industry. Listed in the front of the transcripts of those hearings are various FDA documents that were referred to in testimony.

What the Future Holds

Of all the exemptions to the FOIA, the trade secret exemption is probably the most inhibiting. All experimental data that drug companies gather in developing new drugs and approving their safety, for example, are carefully protected under that exemption.

New legislation, however, would open the approval process

The Freedom of Information Act

Releasable Information

Corrective letters on drug labeling and advertising from company officials, Congress and the public.

Adverse reactions to drugs (names of doctors and patients are confidential).

Informal regulatory actions against drug and cosmetic makers.

Summarized plant inspections.

Initial drug marketing applications.

Operating manuals.

Enforcement actions and all completed reports.

Summarized test data (after a drug is approved).

All FDA research results.

Reports on safety and efficacy of many products.

Scientific information on new products submitted by manufacturers.

Summarized marketing refusals on drugs.

Exempted Information

Trade secrets — regulatory procedures, program guidelines, work plans and other internal instructions involving a company.

Information usually subject to special privilege — doctor-patient or lawyer-client relations, etc. The FDA will not disclose the names of patients and physicians, or personal information about patients. This information is released only "when the need arises" — such as in a public health emergency.

Differences of opinion within the department — staff papers and other information flowing within the agency.

Personnel and medical files — clinical information submitted by investigators, details of patient histories, and training and experience of FDA personnel.

Many enforcement files and records — some factory inspection reports, sample collection and analysis reports, surveillance reports, warning letters and hearing notices.

to public scrutiny by requiring companies to make their data public. The legislation would guarantee them some protection from competition for a few years following the approval.

The proposal has spurred strong industry objections, because manufacturers say it would give any competitor an opportunity to copy an important new drug outside the country and sell it internationally without having to spend the millions of dollars that often go into the development process.

FOOTNOTES

1. Telephone conversation with author, April 1979.
2. Telephone conversation with author, April 1979.
3. Morton Mintz, **By Prescription Only** (Boston: Houghton Mifflin Co., 1967), p. 328.
4. **Ibid.**
5. **Ibid.**
6. Food and Drug Administration, **Annual Report** 1977, p. 5.
7. Scott Lucas, **The FDA** (Millbrae, Calif.: Celestial Arts, 1978), p. 16.